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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/965,610	09/26/2001	Adam S. Cantor	56032US022	8132

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EXAMINER

JOYNES, ROBERT M

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 12/17/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/965,610

Applicant(s)

CANTOR ET AL.

Examiner

Robert M. Joynes

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-33 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Receipt is acknowledged of applicants' Supplemental Information Disclosure Statement filed on August 27, 2002.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 13-15 recite the limitation "the skin permeation enhancer" in line one of each claim. There is insufficient antecedent basis for this limitation in the claim. It appears to the Examiner that the delivery enhancing adjuvant of Claim 10 is also known as the skin permeation enhancer. It is suggested that one term be chosen and used throughout the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garbe et al. (WO 96/08229) in view of Cleary (EP 0483105 A1). Garbe teaches a transdermal drug delivery device comprising a backing and a matrix comprising a copolymer, a softener and a drug (Page 2, lines 5-23). The copolymer comprises one or more A monomers selected from the group consisting of alkyl acrylates containing 4 to 10 carbon atoms in the alkyl group and alkyl methacrylates containing 4 to 10 carbon atoms in the alkyl group; one or more ethylenically unsaturated B monomers copolymerizable with the A monomers and a macromonomer copolymerizable with the A and B monomers (Page 2, lines 5-23). The A monomers are taught on Page 4, lines 3-14. The B monomers are taught on Page 4, line 15 through Page 5, line 12. The macromonomers are taught on Page 5, line 13 through Page 8, line 28. Polymethylmethacrylate macromonomers are preferred (Page 6, lines 17-18). The macromonomer is generally present in an amount of not more than 30% by weight based on the total weight of all monomers in the copolymer (Page 5, lines 2-23).

The softeners of the delivery device include fatty acids, fatty alcohols, fatty acid esters as well as drugs that act as softeners (Page 8, line 29 – Page 10, line 15). Softeners can be included in amounts up to 60% by weight of the matrix (Page 10, lines 7-15).

Garbe further contemplate various drugs for delivery by the device including analgesics such as fentanyl (Page 12, line 7 – Page 13, line 20). The drug is present in the transdermal device in an amount of about 0.01 to about 30 percent by weight (Page 13, lines 16-18). Also, the drug is substantially fully dissolved, and the matrix is substantially free of solid undissolved drug (Page 13, line 18-20).

Garbe does not expressly disclose the exact concentration ranges in the instant claims nor does it teach specifically that fentanyl in the drug delivered. Fentanyl is listed as a possible acceptable drug for transdermal delivery.

Cleary teaches a transdermal delivery device comprising fentanyl and absorption enhancers in a matrix (Page 10, Claims 1-7). The absorption enhancers are fatty acid esters or fatty alcohol ethers (Page 10, Claim 1).

While the reference does not teach the complete concentration range, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 105 USPQ 233, 235 (CCPA 1955).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to prepare a transdermal delivery device wherein a copolymer matrix containing acrylate and methacrylate monomers and a macromonomer further contains fentanyl and enhancing adjuvants. Garbe teaches the delivery device and lists suitable drugs for delivery by the device. Cleary teaches that fentanyl is known to be

delivery transdermally in the presence of absorption enhancing agents. It is obvious to place fentanyl in the delivery device of Garbe.

One of ordinary skill in the art would have been motivated to do this to provide a transdermal drug delivery device that allows dissolution of drug and relatively heavy loading with oily excipients, maintains contact with the skin and can be removed cleanly from the skin.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Joyner whose telephone number is (703) 308-8869. The examiner can normally be reached on Monday through Friday 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3592 for regular communications and (703) 305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.


THURMAN K. PAGE
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